	Implantation	30 days Post-Implantation	60 days Post-Implantation	90 days Post-Implantation	Explantation
Echocardiographic Analysis:					
LVEF (%)	19.3±6.62	43.5±8.51***	40.7±10.9***	36.0±12.7***	-
LVEDD (mmHg)	6.94±1.40	3.31±0.97***	4.42±1.00***	4.90±1.40**	-
LV mass (gm)	-	193±102	192±90.1	220±90.1	-
Tissue Analysis:					
Myocyte Area (μm^2)	562±122	-	-	-	290±63.3***
Myocyte Diameter (μm)	16.9±2.49	-	-	-	13.0±1.87***
% Collagen Deposition	35.7±7.14	-	-	-	27.1±4.27***
Serological Analysis:					
BNP levels (pg/mL)	225±148	63.8±42.7*	-	-	16.3±7.71**
Electrophysiologic Analysis:					
QTc (msec)	472±56.0	448±48.1	434±34.5*	-	461±70.0
QRS (msec)	121±30.4	104±20.3**	104±17.4**	-	114±45.4
Notes: Values are the means ± SD of the listed parameters.	All p-values are for t-tests vs values at implantation.	* p-value < 0.05.	**p-value < 0.01.	***p-value < 0.001.	

1050-122 Outcomes With Patients of Variable Body Surface Area and Long-Term Use of the DeBakey Ventricular Assist Device®

Edward Teitel, Marco Turina, Roland Hetzer, George Noon, Hans Scheld, Ettore Vitali, Ernst Wolner, MicroMed Technology, Inc., Houston, TX

Background: Ventricular assist devices (VADs) are now accepted treatment for end-stage heart failure as bridge-to-transplant.Based on the REMATCH trial, the HeartMate® device has been approved by the FDA for destination therapy. New generation devices offer the hope for smaller, more reliable support as we move to new indications such as destination therapy. The miniaturized, continuous flow DeBakey VAD® has been the most widely used new generation VAD, with over 200 implants worldwide.
Methods: The clinical report forms for completed patients and notes from weekly patient monitoring conferences for ongoing patients were examined on 157 patients at 6 sites in Europe.
Results: At pump speeds ranging from 8-11,500rpm (mean 9600 rpm) regardless of BSA, pump output (mean 4.5 l/min) increased with increasing BSA (slope 1.77)($p < 0.001$). Mean arterial pressures and end organ function, as indicated by BUN, creatinine, and total bilirubin remained in the normal range regardless of BSA. Twenty-five patients were supported > 6 months and 6 patients were supported > 1 year. Of the 25 who were supported > 6 months, 16 (64%) went on to transplant, 2 (8%) are still on support, and 7 (28%) died. Five of the patients on support over a year were transplanted and one died. Forty-three were discharged for a total of 3821 discharge days, or 10.46 patient-years. (2-342 days). (Some patients were not eligible for discharge because of institutional or regulatory constraints.) Twenty-five patients had 50 hospital readmissions. These readmitted patients spent 2974 days out of the hospital (8.15 patient-years). 70% of those discharged, were either transplanted or remain well on long-term support at home.
Conclusion: The DeBakey VAD adequately supports patients from 1.2-2.3 m^2 BSA. DeBakey VAD patients on long-term support can be successfully managed at home with excellent outcomes.

1050-123 Neurological Events With a Totally Implantable Left Ventricular Assist System: The European LionHeart Clinical Utility Baseline Study (CUBS)

John P. Boehmer, Walter E. Pae, Jr., R. Koerfer, A. El-Banayosy, R. Hetzer, M. Vigano, A. Pavie, Penn State Milton S. Hershey Medical Center, Hershey, PA, Bad Oeynhausen Heart Center, Bad Oeynhausen, Germany

We recorded neurological events in patients with end-stage heart failure not eligible for transplant undergoing left ventricular assist device (LVAD) placement with the totally implantable pulsatile LionHeart LVAS as alterntive to medical therapy (AMT).
Twenty-three patients underwent implantation of the LVAS in a non-randomized, observational study. Neurologic events were pre-specified as a class of adverse events, reported by sites, and adjudicated independently. The events were further sub-classified as stroke (CVA), transient ischemic attack (TIA), intracranial bleed (ICB), or other (e.g., brain abscess), and whether they were either permanent/disabling or transient/reversible.
there were 24 neurologic events in 13 patients (56.5%). Nine patients experienced either ICB or CVA, five of which also had a TIA. There were a total of 12 TIAs occuring in eight patients, five of who also had either an ICB or CVA. Three patients were reported to have an "other" neurologic event. A total of 11 patients had either a CVA or a TIA as a primary event, producing an event rate of 0.69 events per pateint-year of follow-up. Placed in terms of functional outcomes, 8 of the LVAD patients had a permanent/disabling neurological injury and 7 had a transient/reversible episode. Importantly, at least 1/3 of events (8/24) occuring in four patients were preventable with improved patient selection and management.
Neurologic events constitute a significant portion of adverse outcomes in this population of AMT following LVAD placement. TIA is the most common neurologic event, with 12 events occuring in eight patients. The incidence is similar to that of the REMATCH LVAD group where 52.9% of patients had neurological dysfunction and 21% were reported to have experienced either an ICB or at least one TIA. Improvements in device design and patient selection as well as management will be needed to reduce the risk of neurologic events in patients supported with LVADs as AMT.

1050-124 Left Ventricular Ejecting Force of the Intra-Aortic Balloon Pump Assisted and Nonassisted Beats

Ashraf W. Khir, Michael Y. Henein, Derek G. Gibson, John R. Pepper, Royal Brompton Hospital, London, United Kingdom, Brunel University, Uxbridge, United Kingdom

Background: The benefits of the Intra Aortic Balloon Pump (IABP) have been widely demonstrated, but the underlying mechanisms of these benefits are not fully described. The left ventricle (LV) ejects the stroke volume with a force that is equal to blood mass multiplied by its acceleration.
Methods: Aortic root, LV early diastolic filling (E-wave) and left anterior descending coronary (LAD) flow velocities were recorded in 20 patients requiring IABP in the intensive care unit using transesophageal Doppler echocardiography. Recordings were made at pumping rates 1:2 and 1:3, leaving a minimum of 15 minutes between recordings to allow for the return to control state. Flow acceleration at the aortic root was calculated as the slope of the early part of the velocity curve and velocity time integral (VTI) was calculated to indicate stroke volume. Diastolic VTI of LAD and LV E-wave velocity curves were also calculated to indicate LAD and LV filling flow.
Results: LAD peak diastolic flow velocity and its VTI increased significantly at IABP 1:2 by (22±2%), (79±15%), and 1:3 by (17±2%), (67±10%) respectively, compared to non assisted beats. LV E-wave peak velocity and its VTI increased significantly at IABP 1:2 by (20±5%), (75±6%), and 1:3 by (11±4%), (60±4%) respectively, compared to non assisted beats. Although a change in flow acceleration at the aortic root was not observed between the assisted and non assisted beats, peak velocity and VTI increased significantly at IABP 1:2 by (25±4%), (35±5%) and 1:3 by (20±3%), (25±4%) respectively, compared to non assisted beats. The increase in LAD diastolic VTI correlated with the increase in diastolic E-wave VTI (r = 0.82), which correlated with the increase in aortic root systolic VTI (r=0.87).
Conclusion: The increase in LAD diastolic flow due to balloon inflation results in an increase in LV filling flow. The increase in LV filling augments the stroke volume ejected into the aorta, which is in agreement with Starling law. The increase in the stroke volume despite the unchanged aortic flow acceleration suggests an increase in the LV ejecting force of the assisted beats, elucidating one of the benefit of IABP.

1050-125 Clinical Application of a Wear-Resistant Axial Flow Pump With an Intelligent Control Algorithm as a Left Ventricular Cardiac Assist Device

Johannes Mueller, Yu-Guo Weng, Torsten Drews, Dagmar Kemper, Evgeni Potapov, Michael Jurmann, Roland Hetzer, Deutsches Herzentrum Berlin, Berlin, Germany

Background: Since the early application of assist devices it has been a goal to have a totally wear-resistant system. INCOR, an axial flow pump for left heart support, has a virtually unlimited life due to magnetic suspension of the rotating impeller. Patients with axial flow pumps show a reduced pulsatility of the blood flow. In order to avoid significant arrhythmia due to sucking in of myocardial tissue INCOR is implemented with an anti-suction control algorithm.
Methods: Out of 72 patients supported with the device since June 2002, 31 (1f, 30m; mean age 53, range 36–65 years) with end-stage heart failure received the system in this institute. Anticoagulation consisted of heparin postoperatively and of Aspirin, clopidogrel, and Warfarin later on. For dosage adjustment, INR, thrombelastography and platelet aggregometry were performed. Furthermore, anti-heart-failure medication was administered.
Results: Mean follow-up is 127 (range, 12-454) days; 19 patients are still being supported. Two patients could be weaned because of cardiac improvement after 178 and 206 days. Two were transplanted and eight died due to multi-organ failure after a mean of 49 (range 22 – 126) days. Three patients showed signs of a transitory ischemic attack and two had cerebral bleeding. Due to the implemented anti-suction algorithm suction did not occur in any patient. After 2 months, blood chemistry showed normal values for all organ functions, in particular no hemolysis (LDH, LDH1 normal) and no deviation of any blood cell count. None of the patients showed signs of infection (CRP normal). Auto-antibodies against cardiac structures like the beta-1-adrenoceptor disappeared within six weeks after the implantation.
Conclusions: Application of up-to-date technology in the design of axial flow pumps significantly improves the clinical outcome. Especially the problems resulting from chronic systemic infection and elevated inflammatory status, known as a major problem of cardiac assist device therapy, seem to be solved. The disappearance of the antibodies after only six weeks is a sign of a fast immunological recovery. No side effects due to reduced pulsatility of the blood could be observed.

1050-126 Left Ventricular Assist Device Implantation in Patients With Viral Myocarditis-Induced Heart Failure

Nicholas C. Dang, Ranjit John, Jeffrey A. Morgan, Brian J. Lee, Mehmet C. Oz, Yoshifumi Naka, Columbia-Presbyterian Medical Center, New York, NY

Background: Viral myocarditis (VM) is a disease entity that exhibits a broad range of clinical pathways to the onset of cardiac symptoms, but the progression to severe congestive heart failure, both chronic and acute, carries significant morbidity and mortality. Left ventricular assist device (LVAD) implantation has gained acceptance as a modality